

REMARKS

This submission is in response to the Official Action dated April 8, 2003.

Claims 47, 73, 79, 80, 81, 96, and 98 have been currently amended. Claims 47, 96, and 98 have been amended in similar fashion to clarify and to emphasize the scope of the invention. Support for the amendments to claims 47, 96, and 98 is as follows:

<u>"and facilitate penetration of said antifungal agent into the nail"</u>	<p>Page 20, lines 11-12; page 19, lines 11-13; page 4, lines 3-6.</p> <p>The amended language rewords the original claim language pertaining to the penetration and clarifies that the antifungal penetrates into the nail.</p>
<u>"water ... to further increase"</u>	<p>Page 19, lines 9-11.</p> <p>The inclusion of the "further" is to emphasize the role of water to increase the permeability of the nail (in addition to the keratolytic agent).</p>
<u>"a liquid nail lacquer component comprising a polymeric film forming agent and a volatile solvent"</u>	<p>Page 19, lines 1-3; page 18, lines 10-14; page 17, lines 2-3; also original claim language.</p> <p>The amended language clarifies the fact that the film forming agent and volatile solvent constitute a liquid lacquer component, as the lacquer may be a solid prior to its dissolution in the solvent.</p>
<u>"said water and said humectant in combination still further facilitating"</u>	<p>Page 18, line 18-page 19, line 1.</p> <p>The amended language emphasizes the role of the humectant with the water to further facilitate the penetration of the antifungal agent (in addition to the keratolytic agent).</p>



Claims 73 has been amended to specify "ethyl cellulose" to simplify the claim. Support for this amendment can be found at page 23, lines 16-17. Claims 79, 80, and 81 have been amended to correct dependency and antecedent basis. New claim 100 has been presented as an alternative to the claim language in claim 47. The same support for amended claim 47 applies to new claim 100, with further support as indicated below:

"a nail afflicted with a fungal infection"	Page 7, lines 16-17.
"said film delivering to said nail water, antifungal agent and keratolytic agent from said composition"	Page 19, lines 9-13.
"for a prolonged period of time"	Page 18, line 14.

Dependent claims 50, 51, 54, 55, 58, 59, 61, 62, 64, 65, 67, 68, 75, 84, 85, 86, and 94, have been canceled, without prejudice or disclaimer to simplify the issues. To the extent broader claims are still pending, they encompass the subject matter of the canceled dependent claims. Therefore, claims 47-49, 52, 53, 56-57, 60, 63, 66, 69-74, 76-83, 87-93, and 95-100 are pending. No new matter has been added by these amendments. Reconsideration of the above identified application, in view of the above amendments and the following remarks, is respectfully requested.

Cancellation of Scheduled Interview and Indication of Allowability

Applicants thank the Examiner and the Primary Examiner for their courteous willingness to prepare for and participate in a telephone interview scheduled for August 27, 2003. At the last minute, the Supervisory Primary Examiner (whose participation had originally been requested) became available. He kindly considered the Applicants' proposed amendments (claims 47, 96 and 98) and summary argument, and advised applicants that the interview would not be necessary and that if the proposed amendment was submitted, the application would be allowed. The Supervisory Primary Examiner specified that he was quite familiar with the differences between skin and nail and that no evidentiary references would be necessary.

Serial No. 09/534,960

Response to Office Action dated April 8, 2003

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Docket No. 3940/OK188



Reiteration of Applicants' Position in Traversing the Rejection

In the Office Action dated April 8, 2003, the Examiner maintained the rejection of claims 47-93, 95-97, and 98-99 under 103(a) as unpatentable over Bohn (U.S. Patent No. 5,264,206) in view of Friedman (U.S. Patent No. 5,160,737).

Applicants have amended the claims only to emphasize and/or to clarify the claimed subject matter. No amendment is made to distinguish over the prior art. Nonetheless, Applicants outline the fact that Friedman is not directed to the treatment of nails and does not disclose a keratolytic agent. Further, applicants submit that treatment of skin (as disclosed in Friedman) is very different from nails in structure, composition and behavior.

Fungal infections of nails are tenacious and difficult to treat. While it may be considered as facilitating nail permeability, water is also recognized as promoting fungal growth (Response 12/17/02, Exhibits B and C respectively, especially MSN page 1, lines 11-30 and Medline page 2, lines 3-7). In the present claims, water is not merely contacted with the nail for a short period of time (until the varnish dries). Instead, it is trapped in a sustained release formulation (absent in Bohn) and further retained therein by a humectant which would further delay its evaporation and prolong contact of water with the nail for a period of time substantially longer than any period of time that untrapped water would be present in contact with the nail in the Bohn formulation. It is therefore counterintuitive to include large amounts of humectant and water in a sustained release nail lacquer formulation, and Friedman (inapplicable to nail lacquers) cannot be used to remedy the deficiency in Bohn.

Applicants submit that it is inappropriate to (i) assume that Friedman applies to nails and (ii) apply teachings about how to treat skin to treatment of nails. Friedman cannot be combined willy nilly with Bohn. Therefore, it would not be obvious to one skilled in the art to use the sustained release film in Friedman in the nail varnish taught by Bohn.

Therefore, in view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.



If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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In re Application of: Michael Friedman; Mohammed S. Safadi

Serial No.: 09/534,960

Examiner : S. Lee Howard

Confirmation No.: 3862

Filed: March 27, 2000

Art Unit: 1615

For: CONTROLLED DELIVERY SYSTEM OF ANTIFUNGAL AND KERATOLYTIC AGENTS FOR LOCAL TREATMENT OF FUNGAL INFECTIONS OF THE NAIL AND SURROUNDING TISSUES

AMENDMENT TRANSMITTAL

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an amendment in the above-identified application. The fee has been calculated as shown below.

(1)

	Claims remaining after amendment	Highest number previously paid for	Present extra	Rate	Additional Fee
Total Claims	37	- 93 =	0	\$18	\$0.00
Independent	5	- 3 =	2	\$84	\$168.00
Multiple Dependent					\$

Total additional fee
for this amendment \$168.00

- Small Entity REDUCTION (Half of preceding total) \$.00
- No additional fee is required.
- A check in the amount of \$.00 is attached.
- Please charge any additional fees up to \$500.00 or credit overpayment to Deposit Account No. 04-0100. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Dated: September 8, 2003

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Serial No. 09/534,960
Amendment Transmittal

Docket No. 3940/OK188

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